Center for Food Safety and Applied Nutrition, shall notify the person submitting the test results whether the tests were conducted in accordance with the ''Analytical Methodology for Polychlorinated Biphenyls; June 1979'', which is incorporated by reference, or the ''Test Procedures for Determination of PCB Permeability of Food Packaging, Inner-Wraps, September 1976, revised May 1983'' and whether, therefore, the barrier or class of barriers is deemed functional within the meaning of paragraph (c) of this section. The test results and any response of the Food and Drug Administration shall be placed on file with the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[42 FR 52819, Sept. 30, 1977, as amended at 44 FR 38340, June 29, 1979; 46 FR 8459, Jan. 27, 1981; 48 FR 10811, Mar. 15, 1983; 48 FR 37021, Aug. 16, 1983; 54 FR 24892, June 12, 1989; 59 FR 14364, Mar. 28, 1994; 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

EFFECTIVE DATE NOTE: At 38 FR 22794, Aug. 24, 1973, the following appeared concerning §109.30(a)(9) (formerly 122.10(a)(9)):
* * * §109.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing. * * *
In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by §109.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973 containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances [Reserved]

Subpart D—Naturally Occurring Posionous or Deleterious Substances [Reserved]

PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

Subpart A—General Provisions

Sec.

Subpart B—Buildings and Facilities

Subpart C—Equipment

Subpart D [Reserved]

Subpart E—Production and Process Controls

Subpart F [Reserved]

Subpart G—Defect Action Levels

AUTHORITY: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

SOURCE: 51 FR 22475, June 19, 1986, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 110 appear at 81 FR 49896, July 29, 2016.

Subpart A—General Provisions

§ 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) *Acid foods or acidified foods* means foods that have an equilibrium pH of 4.6 or below.

(b) *Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) *Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) *Blanching*, except for tree nuts and peanuts, means a prepackaging

heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) *Critical control point* means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) *Food* means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) *Food-contact surfaces* are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ''Food-contact surfaces'' includes utensils and food-contact surfaces of equipment.

(h) *Lot* means the food produced during a period of time indicated by a specific code.

(i) *Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term ''undesirable microorganisms'' includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective ''microbial'' instead of using an adjectival phrase containing the word microorganism.

(j) *Pest* refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) *Plant* means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) *Quality control operation* means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) *Rework* means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) *Safe-moisture level* is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

(o) *Sanitize* means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) *Shall* is used to state mandatory requirements.

(q) *Should* is used to state recommended or advisory procedures or identify recommended equipment.

(r) *Water activity* (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).